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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/277,064 03/26/99 SHERMAN

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HM12/0828

EXAMINER

DAVIS, M

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/277,064

Applicant(s)

Sherman

Examiner

MINH TAM DAVIS

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 25, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 4, 5.

Accordingly, claim 1 being examined.

The following are the remaining rejections.

#### **SPECIFICATION**

Since Applicant requests that submission of a substitute specification be held in abeyance until claims are allowed, requirement of the submission of a substitute specification is delayed until the time of allowance, if the instant application is allowable.

#### **INFORMATION DISCLOSURE STATEMENT**

Since Applicant requests that objections to the information disclosure statement be held in abeyance until claims are allowed, the objections are delayed until the time of allowance, if the instant application is allowable.

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**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH**

Rejection under 35 USC 112, first paragraph of claim 1 pertaining to lack of enablement for SEQ ID NO:12 capable of specifically activating cytotoxic T lymphocytes (CTLs) in patients with tumors expressing Her-2/Neu protein, wherein said CTLs specifically target said tumors in said patients, remains for reasons already of record in paper No.12.

Applicant argues that in view of amendment of claim 1, the rejection should no longer apply.

Applicant's arguments set forth in paper No.14 have been considered but are not deemed to be persuasive for the following reasons:

The amended claim 1 still reads on SEQ ID NO:12 capable of specifically activating cytotoxic T lymphocytes (CTLs) in patients with tumors expressing Her-2/Neu protein, wherein said CTLs specifically target said tumors in said patients, i.e. said CTLs kill tumor cells *in vivo* in patients with said tumors. It is noted that the specification only discloses generation of CTLs in mice without tumor burden, and that the claimed CTLs produced are xenogeneic and kill tumor cells only *in vitro* (specification, p.101). As discussed in previous Office action, Her-2/neu is a self-protein, and that self-tolerance would eliminate T cells that are capable of recognizing Her-2/neu protein with high avidity (Sherman et al, of record). Further, as admitted by Applicant, after some period of time in the presence of tumor cells, T cells could lose their functional activity (specification, p.101); and as taught by Boon et al (of record), even if activated CTLs are significantly increased, the therapeutic success remains unpredictable due to inconsistencies in

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antigen expression or presentation by tumor cells (p.178, paragraph before last paragraph). In addition, one could not extrapolate the *in vitro* tumor cell killing with *in vivo* tumor cell killing due to difference in characteristics of tumor cells *in vitro* as compared to primary tumor cells, difference in *in vitro* and *in vivo* environment, and difference in conditions for targeting tumor cells (Freshney et al, Dermer et al, of record). Thus in view of the above discussion, and further in view of the unpredictability of tumor vaccination and anticancer drug discovery, as overwhelmingly evidenced by Ezzell et al, Spitler et al, Boon et al, Gura et al, Jain et al, Curti et al, and Hartwell et al (of record), it would have been undue experimentation to practice the claimed invention.

#### **REJECTION UNDER 35 USC 102**

Rejection under 35 USC 102(b) of claim 1 pertaining to anticipation by Grey et al or Cheever et al remains for reasons already of record in paper No.12.

Applicant argues that the instant application claims as priority date 12/14/94, the application of the parent case 08/355558. Thus the reference by Cheever et al is not prior art which files on 06/06/1995.

Applicant further argues that Grey et al does not disclose the effect of any antigen, let alone the specific activation of cytotoxic T lymphocytes *in vivo* wherein these lymphocytes specifically target malignant cells that express a human Her-2/Neu protein.

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Applicant's arguments set forth in paper No.14 have been considered but are not deemed to be persuasive for the following reasons:

The priority date could not be determined because neither the specification nor the oath/declaration recites the parent case 08/355558 for claiming as priority date.

Further, Cheever et al claims as priority August 12, 1993, application SN=08/106112, in which the recited SEQ ID NO:56, having 1255 amino acids in length is the same as the claimed polypeptide, i.e. a polypeptide having the amino acid sequence of SEQ ID NO:12.

Concerning the argument against the Grey et al reference, the sequence taught by Grey et al is the exactly same as the claimed SEQ ID NO:12. The reference does not specifically teach that the sequence VMAGVGSPYV, on page 108, sixth sequence specifically activates cytotoxic T lymphocytes *in vivo*, wherein these lymphocytes specifically target malignant cells that express a human Her-2/Neu protein. However, the claimed sequence appears to be the same as the prior art sequence. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art . See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

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August 20, 2001



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